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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/211,315	12/14/1998	WILLIAM J. BOYLE	A-451-G	7234

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/13/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/211,315	Applicant(s) BOYLE, WILLIAM J.	
	Examiner Christopher Nichols, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>516</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. An Advisory Action was mailed on 31 July 2001 (Paper No. 21) in response to Applicant's Amendment filed 28 June 2001 (Paper No. 20). This was an improper action and is hereby **VOIDED**.
2. This Office Action is in response to Applicant's Amendment filed 28 June 2001 (Paper No. 20). This Amendment has been entered in full. Claims 1-36 have been cancelled, claim 42 has been amended, and claims 50-66 have been added. Claims 37-66 are under examination.
3. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1647, Examiner Christopher Nichols.

Withdrawn Objections And/Or Rejections

4. The Declaration of John K. Sullivan under 37 CFR 1.132 filed 21 August 2000 (Paper No. 14) is sufficient to *overcome* the rejection of claims 37-49 based upon 35 U.S.C. §112 ¶1 as set forth at pp. 2-5 ¶5-6 of Office Action (Paper No. 18, 3 January 2001).
5. The reference cited by the Applicant, Yamamoto *et al.* (1988) "Characterization of Mouse Monoclonal Antibodies to Human Interferon-Gamma." Microbiol. Immunol. **32**(4): 339-350 (Exhibit A of Paper No. 20) and Siegel *et al.* (January 1995) "The Mouse/Human Chimeric Monoclonal Antibody cA2 Neutralizes TNF in vitro and Protects Transgenic Mice from cachexia and TNF lethality in vivo." Cytokine **7**(1): 15-25 (Exhibit B of Paper No. 20) have been taken

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into consideration. The Examiner notes that the references offer background information but are not related to the instant invention *per se*.

6. The rejection of claims 37 and 38 under 35 U.S.C. §102(a) as set forth at pp. 5 ¶7-8 of Office Action (Paper No. 18, 3 January 2001) is *withdrawn* in view of "Exhibit A" provided by Applicant in Paper No. 20 (28 June 2001). Applicant is correct, the reference relied upon for the rejection, Tsukii *et al.* "Osteoclast differentiation factor mediates an essential signal for bone resorption induced by 1 alpha,25-dihydroxyvitamin D3, prostaglandin E2, or parathyroid hormone in the microenvironment of bone." Biochem Biophys Res Commun. **246**(2): 337-41, has a post-filing date of *19 May 1998* and therefore is not a valid reference for rejection under 35 U.S.C. §102(a).

7. All rejections and objections not maintained or put forth herein are hereby *withdrawn*.

New Objections And/Or Rejections

Drawings

8. The drawings are objected to because Figures 1 and 4 contain sequence listing without an appropriate SEQ ID NO. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: Figures 5 and 6 contain symbols which are not present in the Specification. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are

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required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

10. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
11. The disclosure is objected to because of the following informalities: the continuity data of the first line of the Specification should be updated, "Application No. 08/880,855 filed 23 June 1997, now abandoned". Appropriate correction is required.
12. The disclosure is objected to because of the following informalities: "mutinucleated" is misspelled (pp. 1 line 31). Appropriate correction is required.
13. The disclosure is objected to because of the following informalities: the status of the following US Patent Applications should be updated (pp. 2 and 7): "Application No. 08/771777, Now Abandoned." And "Application No. 08/660562, Now Abandoned." Appropriate correction is required.

Claim Objections

14. Claims 48, 49, 65, and 66 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

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15. Claims 48 and 62 are objected to because of the following informalities: the claims as written are unclear. The Examiner suggests the following amendments to introduce proper Markush groups into said claims:

Claim 48 (Currently Amended) The method of any one of claims 37-47 further comprising administering a bone morphogenic factor selected from the group consisting of bone morphogenic proteins, BMP-1 to BMP-12, transforming growth factor- β , a transforming growth factor- β family member, a fibroblast growth factor ~~selected from the group consisting of FGF-1 to FGF-10~~, an interleukin-1 inhibitor, a TNF α inhibitor, a parathyroid hormone, an E series prostaglandin, a biosphosphonate, and a bone-enhancing mineral.

Claim 65 (Currently Amended) The method of any one of claims 52-64 further comprising administering a bone morphogenic factor selected from the group consisting of bone morphogenic proteins, BMP-1 to BMP-12, transforming growth factor- β , a transforming growth factor- β family member, a fibroblast growth factor ~~selected from the group consisting of FGF-1 to FGF-10~~, an interleukin-1 inhibitor, a TNF α inhibitor, a parathyroid hormone, an E series prostaglandin, a biosphosphonate, ~~or~~ and a bone-enhancing mineral.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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16. Claims 37 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. The term "modulator" in claims 37 and 52 is a relative term which renders the claim indefinite. The term "modulator" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of what is meant by a "modulator" is not clear.

18. Claims 37 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: to whom and what is administered to fulfill the treatment as set forth by the preambles of said claims.

19. The Examiner suggests the following proposed amendment to overcome 35 U.S.C. §112 ¶2 as set forth herein:

Claim 37 (Currently Amended) A method of inhibiting bone resorption in a mammal comprising administering ~~a modulator of an osteoprotegerin binding protein, wherein the modulator is an~~ antagonist antibody or fragment thereof which binds an osteoprotegerin binding protein to said mammal.

Claim 38 (Cancelled)

Claim 52 (Currently Amended) A method of inhibiting osteoclastogenesis in a mammal comprising administering ~~a modulator of an osteoprotegerin binding protein, wherein the~~

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~~modulator~~ is an antagonist antibody or fragment thereof which binds an osteoprotegerin binding protein to said mammal.

Claim 53 (Cancelled)

Provisional Obvious-Type Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 37-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30-38 of copending Application No. 09/791153 (cited herein by its US Patent Application Publication US 2003/0103978 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 09/791153 are directed to a method of inhibiting osteoclasts formation or activation comprising administering to a mammal an effective amount of a composition comprising an antibody or antigen binding domain, or fragment, variant or derivative thereof, which binds to an osteoprotegerin binding protein and is an antagonist antibody.

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21. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method as detailed in 09/791153 to inhibit osteoclastogenesis as this is commensurate with inhibiting osteoclasts formation or activation. Also the method of 09/791153 encompasses the preamble and essential method steps of the therapy set for by claims 52-66 of the instant application. Further claim 30 of 09/791153 is drawn to a method of inhibiting bone resorption comprising the same steps as summarized above. The method of claim 30 encompasses the preamble and essential method steps of the therapy set for by claims 37-51 of the instant application.

22. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Summary

23. Claims 37-66 are hereby rejected.

24. The following articles, patents, and published patent applications were found by the Examiner during the prior art search and are here made of note:

a. US Patent Application 2003/0104485 A1

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

26. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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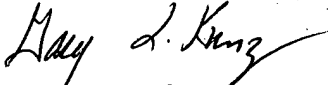
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
August 11, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600